

## ***What to make of bisphosphonate drug risks***

### **What is the problem?**

Recently, there have been some reports of patients with osteoporosis who fracture the bone in the middle of the thigh (between the hip and the knee). This fracture often happens without any major injury. Also patients with this unusual type of fracture often complain of a deep, aching pain in the middle thigh area several weeks to several months before the bone breaks. This mid-thigh fracture is especially unusual because of its location--- the thigh bone is very strong. Most fractures of this bone (the femur) are hip fractures and occur at the upper end, where the femur connects with the pelvis. Only 3-5% of femur fractures occur between the hip and the knee. Medical journals have reported a total of about 100 people with mid-thigh fractures who are taking bisphosphonates such as Actonel®, Boniva®, Fosamax® and Reclast®. Scientists call these “case reports”. Case reports are not rigorous scientific inquiries to find out the causes or risks of a problem, but they do alert physicians to new developments.

### **What do we know?**

The FDA has reviewed the available data and concluded that the data have not shown a clear connection between bisphosphonate use and a risk of mid-thigh fractures. While most bone specialists and scientists would agree with this statement, many people are worried about the potential side effects of bisphosphonate drugs. Scientists are working to gather evidence that will answer questions that have been raised about the safety of the bisphosphonate drugs. Right now, it is too early to know what is really going on in the patients with mid-thigh fractures.

### **How big a problem is it?**

While it is true that a large percentage of the case reports of mid-thigh fractures were in patients taking bisphosphonate drugs, this fracture can also occur in people not using bisphosphonates. We know that over a million patients have taken bisphosphonates since their introduction 15 years ago---so 100 cases are a very small fraction of total users. To date, no reports describe the actual frequency of mid-thigh fractures among patients taking a bisphosphonate drug --- The mid-thigh fracture certainly seems rare and bisphosphonate drugs may not be the cause OR may not be the only cause.

Scientists will have some challenges sorting out the cause of the mid-thigh fracture since people with osteoporosis are prone to fracture. They fracture from a combination of weak bones and having an injury, mostly a fall.

Bisphosphonate drugs really help reduce fracture risk, but they only reduce the risk by about 35% and they do not reduce the risk of falls that cause fractures. There are currently no bone drugs that cure osteoporosis or make the risk of fracture go away completely. This fact makes it hard for scientists to study the safety of bisphosphonate drugs and whether they increase the risk of certain fractures. Looking for a cause to the fracture is like looking for the proverbial “needle in the haystack”.

### **What can you do?**

FIND OUT YOUR FRACTURE RISK. If you are at high risk for a fracture, then these days, taking a bisphosphonate is the best way to reduce the risk. You can learn your fracture risk at [www.americanbonehealth.org](http://www.americanbonehealth.org). If you are taking a bone drug, remember that your risk is reduced by 35%. If you are at low or moderate risk, taking a bisphosphonate may not be a good idea. There are still important other [prevention strategies](#) to keep your bones strong.

BE ALERT TO SIGNS OF A PROBLEM. Many patients who have had mid-thigh fractures report a deep, aching pain in the middle of the thigh several weeks to months before that bone breaks. This ache is not joint pain and not related to activity. If you are taking a bisphosphonate drug and have an aching pain in your mid-thigh, talk to your doctor.

DISCUSS DOSE AND HOLIDAYS. Bisphosphonate drugs work relatively quickly and patients can see benefits within a few years. When you see your doctor, discuss your dose and how long you should take the drug. Depending on your situation, your doctor may consider a “drug holiday” after a few years and then monitor your progress to see if your bone density remains stable without the drug.

### **How can you be sure?**

Learn your fracture risk at [www.americanbonehealth.org](http://www.americanbonehealth.org). This information will help you and your doctor determine whether or not you should be on a treatment that will help prevent fractures.